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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/428,371	10/28/1999	DAVID M. SODERLUND	19603/606-(C)	4568

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ZARA, JANE J

ART UNIT	PAPER NUMBER
1635	17

DATE MAILED: 12/04/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.	09/428,371	Applicant(s)	SODERLUND ET AL.
Examiner	Jane Zara	Art Unit	1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) Responsive to communication(s) filed on 17 September 2001.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) Claim(s) 41-52 and 78-83 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 41-46 and 78-83 is/are allowed.
- 6) Claim(s) 47-52 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

- 12) The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f)
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application)
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) Notice of References Cited (PTO-892)      4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)      5) Notice of Informal Patent Application (PTO-152)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_      6) Other: \_\_\_\_\_

APP

Art Unit: 1635

## **DETAILED ACTION**

This Office action is in response to the communication filed September 17, 2001, Paper No. 16.

Claims 41-52 and 78-83 are pending in the instant application.

### ***Continued Prosecution Application***

The request filed on September 17, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/428,371 is acceptable and a CPA has been established. An action on the CPA follows.

Applicants' request for reconsideration filed September 17, 2001, Paper No. 16, has been noted and is moot in light of the new grounds of rejection as set forth below.

### ***Claim Objections***

Claims 47-52 are objected to because of the following informalities: They depend from a canceled claim (claim 1). Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1635

Claims 47-52 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of screening chemical agents for their ability to modify sodium channel function comprising introducing and expressing in an appropriate host cell an isolated nucleic acid molecule encoding SEQ ID NO: 1 (or nucleic acids which hybridize under conditions delineated in claim 41) and a second nucleic acid molecule encoding a tip E protein, and evaluating the transfected host cell for voltage sensitive sodium channel function modifications after exposing it to a chemical agent, does not reasonably provide enablement for such screening comprising introducing any isolated nucleic acid molecule encoding any voltage sensitive sodium channel (and a second nucleic acid molecule encoding a tip E protein) of *Musca domestica*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to methods of screening chemical agents for their ability to modify sodium channel function comprising introducing and expressing in an appropriate host cell any isolated nucleic acid molecule encoding any voltage sensitive sodium channel of *Musca domestica* and a second nucleic acid molecule encoding a tip E protein, and evaluating the transfected host cell for voltage sensitive sodium channel function modifications after exposing it to a chemical agent.

The following factors have been considered in determining that the specification does not enable the skilled artisan to make and/or use the invention over the scope claimed.

Art Unit: 1635

The specification as filed teaches a method of screening chemical agents for their ability to modify voltage sensitive sodium channel function comprising the transfection and expression of SEQ ID NO: 1 in appropriate host cells, which nucleic acid sequence encodes a voltage sensitive sodium channel, as well as screening for such chemical agents by transfecting mutants of SEQ ID NO: 1 which comprise nucleic acids which hybridize to SEQ ID NO: 1 (nucleotides 1-1011 or 1321-5030) at 42°C in a solution comprising 5 x SSPC and 50% formamide or at 65°C with 0.5 x SSPC, or additionally screening chemical agents as described above in combination with co-expressing a second nucleic acid molecule encoding tip E in the appropriate host cell. The specification as filed fails to teach such screening assays using nucleic acids encoding any and/or all voltage sensitive sodium channels which may exist in *Musca domestica*, or mutants thereof. One skilled in the art would not accept on its face that SEQ ID NO: 1 (or any mutants of nts 1-1011 or 1321-5030 obtained by the hybridization conditions delineated in the appropriate claims) is representative of any and/or all voltage sensitive sodium channels in *Musca domestica* in view of the lack of guidance in the specification and known unpredictability associated with the identification of all voltage sensitive sodium channels in *Musca domestica* whereby any and/or all voltage sensitive sodium channels from *Musca domestica* are identified by their ability to hybridize to SEQ ID NO: 1 under the hybridization conditions specified.

The quantity of experimentation required to practice the invention as claimed would require the identification of nucleic acids which encode any and/or all voltage sensitive sodium channels in *Musca domestica*, functionally expressing them in an appropriate host cell and

Art Unit: 1635

utilizing these nucleic acids in screening assays to identify chemical agents which modify their function, or in combination with co-expressing them with nucleic acids encoding tip E protein in an appropriate host cell. Since the specification fails to provide any particular guidance in this regard, and since determination of these factors for identifying all nucleic acids encoding voltage sensitive sodium channels in an organism is highly unpredictable, it would require undue experimentation to practice the invention over the scope claimed.

***Allowable Subject Matter***

Claims 41-46 and 78-83 are allowed.

Art Unit: 1635

***Conclusion***

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(703) 306-5820**. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

**JZ**

November 29, 2001



ANDREW WANG  
PRIMARY EXAMINER